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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,707

01/19/2007

Osamu Ohara

3190-100

9479

33432 7590 10/15/2008

KILYK & BOWERSOX, P.L.L.C.

400 HOLIDAY COURT

SUITE 102

WARRENTON, VA 20186

EXAMINER

DESAI, ANAND U

ART UNIT

PAPER NUMBER

1656

MAIL DATE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,707	<b>Applicant(s)</b> OHARA ET AL.	
	<b>Examiner</b> ANAND U. DESAI, Ph.D.	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 10-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-9 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20061204;20080812</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1656

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of group I, drawn to a polynucleotide shown by the nucleotide sequence set forth in SEQ ID NO: 1 encoding the a protein shown by the amino acid sequence set forth in SEQ ID NO: 2 in the reply filed on June 12, 2008 is acknowledged.

Applicants state claims 1, 4-9, and 23 read on the elected species. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2, 3, and 10-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species and inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 12, 2008.

3. Claims 1, 4-9, and 23 drawn to a polynucleotide encoding SEQ ID NO: 2 are currently under examination.

### ***Priority***

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application. The priority date is March 31, 2004.

Art Unit: 1656

***Information Disclosure Statement***

5. The information disclosure statements (IDSs) submitted on December 4, 2006 and August 12, 2008 are being considered by the examiner. The signed 1449 forms are attached with the office action.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 4-9, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. In claim 1, what is a polynucleotide shown by the complementary nucleotide sequence of the polynucleotide referring to? What is “the polynucleotide”?

9. In claim 4, what are the homology criteria? Suggest, at least 70% identity if trying to claim a structural identity.

10. In claim 5 how does an induced mutation differ from a mutation?

11. In claim 23, what is a polynucleotide shown by the complementary nucleotide sequence of the polynucleotide referring to? What is “the polynucleotide”?

12. Claims 7-9 are rejected for depending on a rejected claim.

Art Unit: 1656

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 4-9, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Venter et al. (WO 2002/068579 A2).

Venter et al. disclose an isolated nucleic acid molecule that is a polynucleotide set forth in SEQ ID NO: 1. Claim 1 can also be interpreted to read on any polynucleotide set forth in SEQ ID NO: 1, because the phrase a polynucleotide shown by the nucleotide sequence set forth in SEQ ID NO: 1 is interpreted to read on an oligonucleotide of two nucleotides in common from SEQ ID NO: 1. The sequence identity is shown below:

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AFS96924
ID   AFS96924 standard; DNA; 779 BP.
XX
AC   AFS96924;
XX
DT   20-SEP-2007   (first entry)
XX
DE   Human transcript sequence, SEQ ID 16323.
XX
KW   DNA detection; RNA detection; exon; ds.
XX
OS   Homo sapiens.
XX
PN   WO200268579-A2.
XX
PD   06-SEP-2002.
XX
PF   10-JAN-2002; 2002WO-US000284.
XX
PR   10-JAN-2001; 2001US-00756696.
XX
PA   (PEKE ) PE CORP NY.
XX
PI   Venter CJ, Adams M, Li PWD, Myers EW;
XX
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Art Unit: 1656

DR WPI; 2002-682812/73.  
XX  
PT New isolated nucleic acid detection reagent for detecting the presence  
of  
PT specified human exons.  
XX  
PS Claim 4; SEQ ID NO 16323; 40pp; English.  
XX  
CC The present invention relates to a novel isolated nucleic acid detection  
CC reagent for detecting the presence of specified human exons. The exon  
CC sequences cover every identified human transcript and exon comprising  
CC every gene/coding region of the human genome. The present sequence is  
one  
CC such exon sequence. The nucleic acid detection agent is used for  
CC detecting the presence of at least 100000, at least 2000, at least 50000  
CC or at least 10000 human exons. The sequences that span exon-exon  
CC junctions eliminate false signals caused by genomic contamination. This  
CC is because a detection element comprising two neighboring exons as one  
CC contiguous sequence will not hybridize to genomic DNA comprising  
CC intervening intronic DNA. These detection elements will only hybridize  
to  
CC expressed mRNA transcripts in which the exons are connected and the  
CC intronic sequence has been removed, therefore forming one contiguous  
CC stretch of sequence corresponding to the sequence of the detection  
CC element that spans the exon-exon junction.  
XX  
SQ Sequence 779 BP; 193 A; 232 C; 209 G; 145 T; 0 U; 0 Other;

Query Match 71.1%; Score 779; DB 7; Length 779;  
Best Local Similarity 100.0%; Pred. No. 6.4e-186;  
Matches 779; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy	300	CTCCGTGGCCGCCCTGACGGAATGCATGCGGGACAAGCAGCAGGCCAAGTTCTTTCGGGA	359
Db	1	CTCCGTGGCCGCCCTGACGGAATGCATGCGGGACAAGCAGCAGGCCAAGTTCTTTCGGGA	60
Qy	360	CCGGCAGGAGCTGCTACAGCACTCGTGCCCTTGGGCTCCTACCTGCTGAAGCCAGTCCA	419
Db	61	CCGGCAGGAGCTGCTACAGCACTCGTGCCCTTGGGCTCCTACCTGCTGAAGCCAGTCCA	120
Qy	420	GCGCATCCTCAAGTACCACCTGCTGCTCCAGGAAATTGCCAAACATTTTGATGAAGAAGA	479
Db	121	GCGCATCCTCAAGTACCACCTGCTGCTCCAGGAAATTGCCAAACATTTTGATGAAGAAGA	180
Qy	480	GGATGGCTTTGAGGTGGTGGAGGATGCCATTGACACCATGACCTGTGTGGCTGGTACAT	539
Db	181	GGATGGCTTTGAGGTGGTGGAGGATGCCATTGACACCATGACCTGTGTGGCTGGTACAT	240
Qy	540	CAACGACATGAAGAGGAGGCATGAGCACGCGGTCCGGCTCCAGGAGATTCACTACTCCT	599
Db	241	CAACGACATGAAGAGGAGGCATGAGCACGCGGTCCGGCTCCAGGAGATTCACTACTCCT	300
Qy	600	CATCAACTGGAAGGGGCCGACCTGACCACCTACGGGGAGCTTGTCTCTGGAGGGCACATT	659

Art Unit: 1656

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          |||
Db      301 CATCAACTGGAAGGGGCCCCGACCTGACCACCTACGGGGAGCTTGTCTCGGAGGGCACATT 360
          |||
Qy      660 CCGCGTGCATCGCGTGC GCAATGAAAGGACCTTTTTCTCTTTGACAAAACACTGCTTAT 719
          |||
Db      361 CCGCGTGCATCGCGTGC GCAATGAAAGGACCTTTTTCTCTTTGACAAAACACTGCTTAT 420
          |||
Qy      720 CACCAAGAAGCGGGGCGATCACTTTGTCTACAAGGGCAACATCCCGTGCTCCTCCCTGAT 779
          |||
Db      421 CACCAAGAAGCGGGGCGATCACTTTGTCTACAAGGGCAACATCCCGTGCTCCTCCCTGAT 480
          |||
Qy      780 GCTGATCGAAAGCACCAGAGACTCCCTGTGCTTCACTGTCACCCACTACAAGCACAGCAA 839
          |||
Db      481 GCTGATCGAAAGCACCAGAGACTCCCTGTGCTTCACTGTCACCCACTACAAGCACAGCAA 540
          |||
Qy      840 GCAGCAGTACAGCATCCAGGCCAAGACAGTGGAGGAGAAACGGAAGTGGACTCACCACAT 899
          |||
Db      541 GCAGCAGTACAGCATCCAGGCCAAGACAGTGGAGGAGAAACGGAAGTGGACTCACCACAT 600
          |||
Qy      900 CAAGAGGCTCATCCTAGAGAACCACCATGCCACCATTCCCCAGAAGGCCAAGGAAGCCAT 959
          |||
Db      601 CAAGAGGCTCATCCTAGAGAACCACCATGCCACCATTCCCCAGAAGGCCAAGGAAGCCAT 660
          |||
Qy      960 CTTGGAAATGGATTCTTATTATCCCAATCGGTACCGCTGCAGCCCAGAGCGGCTGAAGAA 1019
          |||
Db      661 CTTGGAAATGGATTCTTATTATCCCAATCGGTACCGCTGCAGCCCAGAGCGGCTGAAGAA 720
          |||
Qy      1020 GGCTTGGTCCTCCCAGGATGAGGTGTCCACCAATGTGCGCCAGGGGCGCCGGCAATCTG 1078
          |||
Db      721 GGCTTGGTCCTCCCAGGATGAGGTGTCCACCAATGTGCGCCAGGGGCGCCGGCAATCTG 779

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Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Art Unit: 1656

***Claim Objections***

15. Claims 1 and 23 are objected to because of the following informalities:
16. In claims 1 and 23 suggest using the standard Markush terminology, ...polynucleotide selected from the group consisting of A, B, and C.

Appropriate correction is required.

***Conclusion***

17. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI, Ph.D. whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

October 11, 2008

/ANAND U DESAI, Ph.D./

Examiner, Art Unit 1656